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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,362	06/25/2001	George M. Grass	109904-00028	6261

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EXAMINER
LY, CHEYNE D

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,362	GRASS ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 27, 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traversal of Group I, claims 1-17, Specie A (gastrointestinal tract), in Paper No. 7, filed February 27, 2003, is acknowledged.

2. Claims 1-17, Specie A (gastrointestinal tract) are examined on the merits.

Information Disclosure Statement

3. Document CL has not been considered due to said document being not present in the instant application.

4. Documents EF-EJ have not been considered due to said documents being non-published documents.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Specific to claims 1 and 5, (ii), line 1, the term "desired" causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine that an absorption profile is desirable (by color or numerical value). Clarification of the metes and bounds is required. Claims 2-4 and 6-17 are rejected due to being directly or indirectly dependent from claim 1 or 5.

CLAIM REJECTIONS - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 4, 7, 8, 12, and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hale et al. (US 5,607,691 A).

10. Hale et al. disclsoes a method for screening a compound library (columns 31-32, vi. Screening Procedures §) by absorption wherein the rate of transdermal pharmaceutical agent absorption is primarily determined by the agent's lipid solubility (column 1, lines 67-68). More specifically, Hale et al. discloses the absorption of agent as directed to the gastrointestinal surfaces (column 1, lines 42-48), as in instant claim 12.

11. "Few pharmaceutical agents fit this profile and those which do are not always predictably absorbed" (column 2, lines 5-7). The recommended administered dosage (initial dose) is less than 50 mg/day (column 11, lines 45-51). "Typically, this library will be synthesized in a solid-state format with each modifier bound to a substrate via a cleavable linker. The compound can then be cleaved from the substrate and screened in vitro as to their transport or other characteristics." The screening procedure is repeated to optimized for generating the pharmaceutical agent (columns 31-32, Screening Procedures §). The first and secondary libraries are disclosed in Tables 1 and 2 where the compounds are selected, as in instant claim 13.

12. The properties characterized by human in vivo and in vitro cell based assays include membrane transport rate, delivery rate, serum half-life, and biodistribution, including the enhancement of pharmacokinetic and pharmacodynamic properties, such as lipophilicity and/or solubility, and partition coefficient (column 44, lines 45-67 to column 46, lines 1-24), as in instant claims 1, 3, 7, and 8.

13. 5-Fluorouracil is is an antineoplastic antimetabolite wherein there is evidence that the metabolism of fluorouracil in the anabolic pathway blocks the methylation reaction of deoxyuridylic acid to thymidylic acid (column 22, lines 33-38), as in instant claim 4.

CLAIM REJECTIONS - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hale et al. (US 5,607,691 A) taken with Yang et al. (1994) in view of Jacobson et al. (US 5,773,423 A).

17. Hale et al. discloses the limitation of claims 1, 3, 4, 7, 8, 12, and 13 as discussed above.

18. However, the method of Hale et al. is not limited to a computer-implemented pharmacokinetic tool or structure relationship information.

19. Jacobson et al. discloses a compound screening procedure (column 8, lines 14-16) for improving pharmacokinetic investigations (column 26, lines 51-52) wherein the biological activity of compounds are unknown (column 5, lines 29-37), binding assay is used to study structure activity relationship and the method is computer implemented (Example 35, specifically columns 40, lines 59-61 and column 42, lines 10-19), as in instant claims 9-11 and 14.

20. Further, the method of Jacobson et al. comprises statistical error determination and control (column 51, lines 59-61, column 52, lines 5-19, and Figure 2), as in instant claim 6.

21. Yang et al. discloses the pharmacokinetic investigations comprising computer readable components for modeling and simulations requiring data input (pages 63-71). More specifically, the input data is directed to information about dose response and toxicity (page 65, § 3.4.1, lines 5-14), and a graphical profile is generated as an output (Figure 3.8) as in instant claims 2, 5, and 15-17.

22. The method of Yang et al. comprises differential equations requiring physiological parameters, adjustment parameters, and correlation parameters (page 63-65, §3.3.5), as in instant claim 6.

23. Jacobson et al. discloses a compound screening procedure (column 8, lines 14-16) for improving pharmacokinetic investigations (column 26, lines 51-52) and Yang et al. discloses pharmacokinetic investigations comprising computer readable components for modeling and simulations (pages 63-71). While, Hale et al. disclose a method for screening a compound library (columns 31-32, vi. Screening Procedures §) as directed to pharmacokinetic investigations (column 44, lines 45-67 to column 46, lines 1-24). Thus, the improvements suggested by Jacobson et al. are directly applicable to the pharmacokinetic investigations of Hale et al. and Yang et al.

24. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the concept emphasized by Jacobson et al. for improving pharmacokinetic investigations. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method for screening a compound library as taught by Hale et al. and improve on the concept by performing the computer-implemented method as directed to pharmacokinetic investigations as taught by Yang et al. and Jacobson et al.

CONCLUSION

25. NO CLAIM IS ALLOWED.

26. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

29. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
9/4/03

ARDIN H. MARSCHEL
PRIMARY EXAMINER